

REMARKS

Claims 1, 13, and 29 are amended and new claim 39 added. Claims 11-12, 19-28, and 37-38 were previously cancelled. Claims 1-10, 13-20, 29-36, and 39 are pending for the Examiner's review and consideration. The amendments to the claims are fully supported by the original specification and claims. Specifically, the amendments to claims 1, 13, and 29 are supported at paragraphs [0072], [0083], [0112-17], and [0125-27] for example and Figures 2-9. The paragraph numbering used herein is in accordance with the USPTO publication of the application, Publication No. 2004/0216193. No new matter has been added by the amendments made herein. Entry of the amendments at this time is therefore respectfully requested.

Claim Rejections

Claims 1-10, 13-20 and 29-36 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement for the reasons set forth on pages 3-6 of the Office Action. Applicant traverses.

The test for whether a specification has met the written description requirements is whether the specification conveys with reasonable clarity to those skilled in the art that Applicant was in possession of the invention as claimed as of the filing date. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). A description as filed is presumed to be adequate. See MPEP 2163.04.

Finally, it is important to understand that the written description requirement does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998).

In view of the written description requirements, Applicant narrowed the scope of the claims. The newly amended claims are directed to a method of producing an angiospermous apomorphic plant in the Poaceae or Asteraceae family having an increased genetic stability for apomixis. The method involves the step of producing the facultatively apomorphic plant by: cytoembryologically identifying and hybridizing sexual plants in the Poaceae or Asteraceae family having divergent reproductive schedules of ovule development. The claims now further specifically require the cytoembryological identification and selection of sexual plants as taught by the present specification and working examples and the step of selecting a hybrid plant that is facultatively apomorphic to be the apomorphic parent plant followed by doubling the chromosome number or modifying the facultative apomorphic plant produced so that female meiosis is aborted.

The original specification clearly teaches and describes how this is to be done in such a way that one skilled in the art would understand that Applicant was in possession of the invention at the time of filing. *See, e.g., Example 1, paragraphs [0112-13]; Example 3, paragraph [0127]; Figures 2-5 showing the step of cytoembryologically identifying sexual plants from the Poaceae or Asteraceae family having divergent reproductive schedules of ovule development and hybridization of same. Specifically, Figure 2 shows megasporocyte and dyad of *A. umbrinella* and *A. racemosa*; Figure 3 shows the variation of female reproductive schedules of microscopic ovule tissues for nine different *Antenaria* spp.; Figure 4 the duration of meiosis for 17 ecologically diverse sorghum land races and the mean inner integument length at the dyad stage of meiosis for sorghum -- microscopically determined following the teaching set forth in Applicant's specification. In Example 2, at paragraphs [0114-0118], Applicant provides a working example of successfully increasing the genetic stability for apomixis in a facultative apomict-- by hybridizing this plant with *T. zopilotense* (2x sexual) or *T. bravum* (2x sexual) a stable obligate apomict with about 80% diplosporous embryo sac formation and 20% abortive meiocyte or sexual embryo sac formation is produced (FIG. 9). Finally, Applicant previously submitted a 1.132 declaration providing even further evidence of the effectiveness of the methods disclosed in possession of the invention as taught and disclosed by Applicant in the original specification.*

In view of the narrowing amendments made herein, Applicant's detailed disclosure and the working examples in the Poaceae and Asteraceae family using Applicant's

claimed invention, one skilled in the art would reasonably conclude that the inventor had possession of the invention at the time of filing as set forth in the presently amended claims. Applicant therefore respectfully requests that this rejection be withdrawn.

Claims 1-10; 13-20 and 29-36 were also rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirements for the reasons set forth on pages 6-10 of the Office Action. Applicant respectfully request reconsideration.

The test of enablement is whether the "disclosure coupled with information known in the art provides sufficient information to one reasonably skilled in the art to make or use the invention without undue experimentation." *United States v. Telelectronics, Inc.*, 857 F.2d 778, 785, (Fed. Cir. 1988). Reasonable and routine experimentation is not undue experimentation. In fact, even if the experimentation is complex it does not necessarily make it undue, if the art typically engages in such experimentation. *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104 (Fed. Cir. 1985).

There are many factors to be considered when determining whether any necessary experimentation is "undue." These factors include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). It is improper to conclude that a disclosure is not enabling based on only one of the above factors. MPEP § 2164.01 (a).

In continuation with Applicant's response of December 23, 2005, Applicant provides the following analysis of enablement. In an effort to simplify the issues, Applicant addresses only those factors raised by the Examiner in the final Office Action. For discussion of the other factors, please see Applicant's previous response.

Breadth of the Claims

Applicant has amended the claims herein to narrow the claims. The new claims encompass the working examples of plants from the Poaceae and Asteraceae families provided

by Applicant in the specification and further evidenced by 1.132 declaration previously submitted. Applicant's presently claimed method comprises the steps of (1) producing a facultatively apomorphic parent plant from sexual plants in the Poaceae or Asteraceae family and (2) increasing the genetic stability of the facultatively apomorphic parent plant produced. As specified by the narrowed claims, step 1 is accomplished by:

- a) selecting sexual plants from an angiospermous plant species, genus, or family, wherein the sexual plants are selected from the Poaceae or Asteraceae family;
- b) cytoembryologically identifying sexual plants from the selected plants having divergent reproductive schedules of ovule development such that initiation of embryo sac formation in one sexual plant occurs at about the same time as or before meiosis in the other sexual plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues selected from the group consisting of nucellus, integument, pericarp, hypanthium, and pistil wall;
- c) hybridizing the identified sexual plants having divergent reproductive schedules of ovule development;
- d) recovering hybrid seed therefrom;
- e) sowing the hybrid seed; and
- f) selecting a hybrid plant that is apomorphic to be the apomorphic parent plant.

Furthermore, Step 2 is accomplished by either doubling the chromosome number of the facultative apomorphic plant produced or by genetically modifying the apomorphic plant produced so that female meiosis is aborted.

As can be seen above, the amended claims have been narrowed and are now directed to the hybridization of plants from the Poaceae or Asteraceae family not just any hybridization. Further, the hybridization requires specific steps. For example, the claim now requires cytoembryological identification of sexual plants having divergent reproductive schedules of ovule development, meaning that initiation of embryo sac formation in one sexual plant occurs at about the same time as or before meiosis in the other sexual plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues and further define the nongametophytic ovule and ovary tissues as tissue selected from the group consisting of nucellus,

integument, pericarp, hypanthium, and pistil wall. The specification clearly teaches one skilled in the art how to use known cytoembryological techniques to identify sexual plants having divergent reproductive schedules of ovule development, especially if limited to the Poaceae or Asteraceae families as shown in the working examples. See Example 1-5 of the present application.

In view of the amendments made herein, the claims have been narrowed and are supported by working examples provided by Applicant.

Existence of Working Examples

Applicant provides several working examples of successfully increasing the genetic stability of apomixis in a facultative apomictic plant from the Poaceae and Asteraceae family. In Example 2, at paragraphs [0114-0118], the synthetic amphiploid of diploid *Tripsacum laxum* (2x sexual) x *T. pilosum* (2x sexual) is provided with 50% diplosporous embryo sac formation (FIG. 8). By hybridizing this plant with *T. zopilotense* (2x sexual) or *T. bravum* (2x sexual) a stable obligate apomict is produced with about 80% diplosporous embryo sac formation and 20% abortive meiocyte or sexual embryo sac formation is produced (FIG. 9). Since this plant fails to produce seeds sexually (sexual seed abortion conferred through odd ploidy), it is genetically stable for apomixis – *i.e.*, there is no segregation of the genes causing apomixis through meiosis. Also see the priority application – U.S. Patent No. 6,750,376 (FIGS. 3 and 4; Example 3 and Example 5).

Additional examples were provided in the previously submitted Declaration of John G. Carman under 37 C.F.R. §1.132 declaration pages 10-23. In this Declaration, Dr. Carman disclosed successful production of a facultatively apomictic plants in Asteraceae family (*Antennaria spp.*) and Poaceae family (*Sorghum spp.* and *Tripsacum spp.*) plants using the methods described in the present application.

Level of One of Ordinary Skill

As previously pointed out, the level of skill of a person of ordinary skill in the art is relatively high. A person of ordinary skill in the art as of the filing date of the invention would know how to conduct cytoembryological analyses of plants identifying initiation of embryo sac

formation, developmental maturity of the nongametophytic ovule and ovary tissues using well known cytoembryological techniques as taught by the specification; hybridize selected sexual plant lines by plant breeding; recover seed from the hybridization, sow and raise plants from the seed; identify facultatively apomorphic progeny; chromosome double, B_{III} hybridize; and/or intrograde meiotic mutations. See, for example, Y. Savidan, *Genetics and Utilization of Apomixis for the Improvement of Guineagrass (Panicum maximum Jacq)*, Proc XIV Int. Grassl. Congr., Lexington, KY, 1981, 182 184 (1983); S. Lutts et al., *Male and Female Sporogenesis and Gametogenesis in Apomorphic Brachiaria brizantha, Brachiaria decumbens and F1 Hybrids with Sexual Colchicine Induced Tetraploid Brachiaria ruziziensis*. 78 Euphytica 19 25 (1994). J. Torabinejad et al., *Morphology and Genome Analyses of Interspecific Hybrids of Elymus scabrus*, 29 Genome 150-55 (1987). O. Leblanc et al., *Chromosome Doubling in Tripsacum: the Production of Artificial, Sexual Tetraploid Plants*, 114 Plant Breed. 226-30 (1995); Cohen & Yao, *In Vitro Chromosome Doubling of Nine Zantedeschia Cultivars*, 47 Plant Cell Tiss. Org. Cult. 43-49 (1996); Chalak & Legave, *Oryzalin Combined with Adventitious Regeneration for an Efficient Chromosome Doubling of Trihaploid Kiwifruit*, 16 Plant Cell Rep. 97-100 (1996)."

In view of the newly amended claims directed specifically to hybridization of plants in the Poaceae or Asteraceae family, the working examples of plants in both of these families, and Applicant's teaching provided in the specification one would be enabled to use the presently claimed method without undue experimentation.

Level of Predictability in the Art

As previously stated, the procedures used in Applicant's presently claimed invention are well known in the art. The techniques have been used for years and while some are tedious and require multiple applications at time, they are proven and predictable techniques used by skilled plant breeders. Further more, Applicant provided evidence of the predictability of Applicant's invention, in a 1.132 Declaration that showed three successes obtained in three attempts at producing apomorphic hybrids in the Poaceae and Asteraceae families, e.g., *Antennaria*, *Sorghum* and *Tripsacum*, using the methods taught and disclosed by Applicant in the original specification.

The techniques used in the presently claimed invention are well known and predictably used. This in light of Applicant's significant direction provided in the specification and working examples, would provide sufficient teachings and examples that one reasonably skilled in the art of plant hybridization would be enabled to produce a facultative apomorphic plant in the Poaceae and Asteraceae families and to increase the genetic stability for apomixis of the plant produced without undue experimentation. Applicant's original disclosure teaches and provides examples of the presently claimed invention. In addition, Applicant fully disclosed and taught this step in the parent application U.S. Application No. 09/576,623, filed May 23, 2000, which has now issued as U.S. Patent No. 6,750,376 and is expressly incorporated by reference.

Specifically, the disclosure sets forth Applicant's method of identifying and hybridizing sexual plants having divergent reproductive schedules of ovule development in order to produce facultatively apomorphic plants in the Poaceae and Asteraceae families. The disclosure more specifically teaches that the divergent reproductive schedules of ovule development between the plants should be such that initiation of embryo sac formation in one sexual plant should occur at about the same time as or before meiosis in the other sexual plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues selected from the group consisting of nucellus, integument, pericarp, hypanthium, and pistil wall, even providing pictures as examples to one skilled in the art. See also Examples 5-9 and all Examples in the priority application – U.S. Patent No. 6,750,376.

Applicant further teaches and provides examples of the step of increasing the genetic stability for apomixis of the facultatively apomorphic parent plant produced in the first step. See paragraphs [0089-108] and Example 2. Stabilizing apomixis refers to minimizing the occurrence of sexual revertants from the facultatively apomorphic parent plant. Facultative apomicts, by name are genetically unstable, meaning they produce sexual segregants as a result of facultative sexual reproduction. Applicant provides several methods by which the genetic stability for apomixis can be increased in the facultative apomict. Applicant teaches that this can be done by either making the plant an obligate apomict (preventing sexual reproduction) or by minimizing segregation of the genes causing apomixis (e.g., doubling the chromosome number).

The application contains a thorough explanation of how the present duplicate-gene asynchrony approach to making apomorphic plants is consistent with the observations that

have been made in the apomixis field over many years and further explains why the theories and assumption of the prior art are deficient. Once it is understood by a person skilled in the art of plant breeding how apomixis arises, it is a routine matter to produce polyploids by chromosome doubling or B_{III} hybridization, for example, such that genetic segregation is suppressed.

In view of Applicant's narrowing amendments to only those plants in the Poaceae and Asteraceae family and the working examples provided by Applicant, the great preponderance of the evidence weighs in favor of a finding of an enabling disclosure. While some experimentation may be necessary to use the method as presently claimed, the experimentation would not be "undue" experimentation in the Poaceae and Asteraceae families. For these reasons, it is respectfully requested that this rejection be withdrawn.

Claims 1-10, 13-18, 29-36 were rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as being obvious over Lutts *et al.* (Euphytica 78: 19-25 (1994)) for the reasons set forth on pages 15-16. Applicant respectfully traverses.

Applicant's invention is directed to a unique method of first producing an angiospermous apomorphic plant from selected sexual plants using cytoembryological identification techniques taught by Applicant and then second increasing the stability for apomixis compared to the apomorphic parent plant.

Neither of these steps are taught or suggested by Lutts, alone and definitely not in combination. For example, the first step of Applicant's presently claimed method requires the producing of a facultatively apomorphic plant by:

- (i) selecting sexual plants from the Poaceae or Asteraceae family;
- (ii) cytoembryologically identifying sexual plants from the selected plants having divergent reproductive schedules of ovule development such that initiation of embryo sac formation in one sexual plant occurs at about the same time as or before meiosis in the other sexual plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues selected from the group consisting of: nucellus, integument, pericarp, hypanthium, and pistil wall; and
- (iii) hybridizing the identified sexual plants having divergent reproductive schedules of ovule development;
- (iv) recovering hybrid seed therefrom;
- (v) sowing the hybrid seed; and

(vi) selecting a hybrid plant that is apomictic to be the apomictic parent plant.

In contrast to Applicant's presently claimed invention, Lutts used apomictic plants found in nature and did not cytoembryologically identify sexual plants and then hybridize the identified sexual plants. Lutts simply chromosome doubled a sexual diploid to make sexual tetraploid and then hybridized the resulting sexual tetraploid to a naturally occurring apomictic polyploid. Nowhere in Lutts is Applicant's presently claimed method taught or suggested. Nowhere in Lutts is the step of cytoembryologically identifying and selecting sexual plants having divergent reproductive schedules of ovule development such that initiation of embryo sac formation in one sexual plant occurs at about the same time as or before meiosis in the other sexual plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues selected from the group consisting of: nucellus, integument, pericarp, hypanthium, and pistil wall taught or suggested.

It is important to understand that Lutts did not produce a new facultatively apomictic plant using only sexual parent plants as uniquely taught and claimed by Applicant. Not only does Lutts fail to teach the elements of Applicants first step of producing a new apomictic plant hybridizing the uniquely selected sexual plants, but Lutts further does not teach the concept of stabilization of the newly produced apomict. In fact, there was and would be no need to stabilize the plants in Lutts, as the plants used in Lutts were already genetically stable for apomixis as found in nature. Thus, there would be no motivation to perform Applicant's second step of stabilization either.

In stark contrast to the teachings of Lutts, Applicants specification describes and teaches one skilled in the art how to produce a new facultatively apomictic plant from sexual plants using cytoembryological identification techniques taught by Applicant to select sexual plants having divergent reproductive schedules of ovule development and hybridizing the identified plants. It is only, after the facultatively apomictic plant is produced, that Applicant then uses the second step to increase the genetic stability for apomixis of the newly produced apomictic plant by doubling the chromosome number or genetically modifying the apomictic plant to cause meiosis to abort – thereby stabilizing the newly produced apomictic plant.

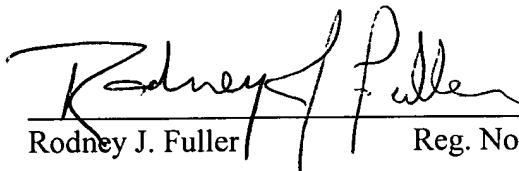
As Lutts fails to teach or suggest each and every element of Applicant's presently claimed method as explained above, Lutts cannot properly be found to anticipate or make obvious

the presently claimed method. For these reasons, Applicant respectfully requests that this rejection be withdrawn.

In view of the above amendments and arguments, Applicant now believes all claims to be in condition for allowance. If there are any questions, the Examiner is invited to call Applicant's representative Rodney Fuller at (602) 916-5404 to resolve any remaining issues to expedite the allowance of this application.

Respectfully submitted,

Date: September 21, 2006



Rodney J. Fuller

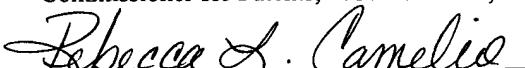
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Rebecca L. Camelio, IP Legal Assistant

September 21, 2006
Date of Signature